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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,317	07/18/2001	Betty P. Tsao	18810-82152	5671

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,317	TSAO ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0202*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted the paper and computer readable forms of the Sequence Listing filed July 18, 2001 have been entered.

Priority

2. It is noted that this application is a continuation-in-part of application no. 09/280,181, now U.S. Patent 6,280,941. Applicant's specific reference to the '181 application in the first line of the specification should be updated to provide the status of that application (i.e., to indicate that the '181 application is "now U.S. Patent No. 6,280,941"). The reference to the '181 application on page 9 of the specification should also be updated.

Information Disclosure Statement

3. The information disclosure statement filed February 1, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, a copy of reference no. 58 (Drake, C.G. et al) was not provided, as the paper submitted by Applicant in parent application 09/280,181 included the reference citation, but not the abstract. Further, a copy of foreign patent document FR 2707 011 A has not been provided. Accordingly, these references have not been considered.

Specification

4. The use of the trademarks ABI PRISM, GENESCAN, GENOTYPER, and GENBANK has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 are indefinite over the recitation of the phrase "wherein said CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, corresponding to nucleotide positions 846 through 869 of (SEQ. ID. NO.: 5)" in claim 1. The claims as written require detection of a CA dinucleotide repeat in "amplification products," not in a "genomic sequence," and it is therefore unclear as to how this phrase further limits the claims. For example, how can a sequence detected in amplification products be located in a genomic sequence? Further, the claims are not written so as to require the presence of SEQ ID NO: 5, and it is unclear as to how one could or would identify nucleotides "corresponding to"

particular positions of SEQ ID NO: 5 in the absence of SEQ ID NO: 5 itself. Clarification is required.

Similarly, claim 2 is further indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotides 845 and 869 of (SEQ. ID. NO.: 5)." The claim as written requires detection of a CA dinucleotide repeat in "amplification products," not in a "genomic sequence," and it is therefore unclear as to how this phrase further limits the claim. Additionally, the claim is not written so as to require the presence of SEQ ID NO: 5, and it is unclear as to how one could or would identify nucleotides located in SEQ ID NO: 5 in the absence of SEQ ID NO: 5 itself. Clarification is required.

Claims 9 and 19 are indefinite over the recitation of the trademarks SYBR and YO-PRO in the claims. A trademark cannot be used property to identify a particular material or product, but rather identifies a source or origin of a product (MPEP 2173.05(u)). As the actual product or material that corresponds to a trademark may change, the use of SYBR and YO-PRO in the claims renders the claims vague and indefinite.

Claims 10-11 are indefinite over the recitation of the terms "PARP-specific nucleotide sequence," "PARP-specific sequence" and "PARP-specific amplification product," as it is unclear as to what would distinguish a sequence or product that is "PARP-specific' from one that is not. While page 14 of the specification indicates that "PARP-specific polynucleotides are determined by base sequence similarity or

homology to (SEQ. ID. NO.: 5)," a clear and limiting definition of this terminology is not provided. Further, page 14 of the specification indicates that a sequence having as few as 5 contiguous nucleotides may be considered a "PARP-specific polynucleotide sequence;" however, the art teaches numerous unrelated molecules including such short sequences present in SEQ ID NO: 5 that clearly could not be employed in specific detection of PARP. Accordingly, the manner in which the language "PARP-specific" limits the claims is unclear.

Claims 10-11 are indefinite over the recitation of the phrase "about 15 to about 30 nucleotides in length, and having a PARP-specific sequence of (SEQ. ID. NO.:5) entirely 5' to nucleotide position 846 of (SEQ. ID. NO.:5)" in claim 10, because it is unclear as to whether this recitation modifies the previously recited "forward primer" or the previously recited "PARP-specific nucleotide sequence." Clarification is required.

Claims 12-19 are indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotide positions 845 and 869 of (SEQ. ID. NO.: 5)" in claim 12. The claims as written require detection of a CA dinucleotide repeat in "amplification products," not in a "genomic sequence," and it is therefore unclear as to how this phrase further limits the claims. For example, how can a sequence detected in amplification products be located in a genomic sequence? Further, the claims are not written so as to require the presence of SEQ ID NO: 5, and it is unclear as to how one could or would identify nucleotides between particular positions of SEQ ID NO: 5 in the absence of SEQ ID NO: 5 itself. Clarification is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fougerousse et al (Nucleic Acids Res. 20(5):1166 [1992]) in view of Ahern (The Scientist 9(15):20).

It is noted that the intended use recited in claim 10 ("for detecting in a human subject a genetic susceptibility to SLE") does not result in a structural difference between the claimed invention and the prior art, and therefore is not accorded patentable weight (see MPEP 2111.02).

Fougerousse et al teach a primer pair that may be used in specific amplification of a dinucleotide repeat starting at position 845 of the PARP gene (see entire abstract).

The primer pair disclosed by Fougerousse et al includes a primer (identified as the "TG strand" primer) that is 100% identical to instant SEQ ID NO: 2. Additionally, the "CA strand" primer of Fougerousse et al, which is 20 nucleotides in length, is 100% identical to nucleotides 825-844 of instant SEQ ID NO: 5. It is a property of the primer pair of Fougerousse et al that it may be used in PCR to produce a "PARP-specific amplification product," as required by the claims. Accordingly, the primer pair of Fougerousse et al meets the structural and functional requirements of the primer set of claim 10, and further, the "TG strand" primer of Fougerousse et al constitutes a reverse primer identical to instant SEQ ID NO: 2, thereby meeting the requirements of claim 11. Fougerousse et al do not teach packaging their primer pair into a kit, and further do not teach a kit including instructions. Ahern teaches that premade reagents provided in kit form are convenient and save researchers time and money, and further teaches the inclusion in kits of "detailed instructions to follow" (see p. 3/5-4/5). In view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Fougerousse et al so as to have packaged the primer pair taught by Fougerousse et al into a kit, and so as to have included instructions in said kit, as suggested by Ahern. An ordinary artisan would have been motivated to have made such a modification in order to have provided the reagents and instructions needed to perform Fougerousse et al's genetic testing method to practitioners in a convenient format, for the advantages of efficiency and cost-effectiveness.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-9 and 12-19 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,280,941 B1. An obviousness type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). In the instant case, although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-9 and 12-19 of the instant application are generic to all that is recited in claims 1-4 of the '941 patent. That is, claims 1-4 of the '941 patent fall entirely within the scope of claims 1-9 and 12-19, or, in other words, claims 1-9 and 12-19 are anticipated by claims 1-5, respectively.

In particular, it is noted that both sets of claims recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition, and that the primers of '941 claims 1-4 are the same as those of instant dependent claims 5-7 and 15-17. Thus, claims 1-4 of the '941 patent anticipate instant claims 1-9 and 12-19.

12. Claims 10-11 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7 of U.S. Patent No. 6,280,941 B1 in view of Ahern.

Claims 10-11 of the instant application are drawn to kits comprising a primer set and instructions, wherein SEQ ID NOS 1-2 of the application meet the requirements of the primer set, as evidenced by the text of claim 11. It is noted that SEQ ID NOS 1-2 of the instant application are identical to SEQ ID NOS 1-2 of the '941 patent. Claims 5-7 of the '941 patent are drawn to a primer comprising SEQ ID NO: 1, a primer set including SEQ ID NOS 1 and 2, and a kit comprising the primer set. The '941 claims do not recite the inclusion of instructions in the kit of the claims. However, Ahern discloses the inclusion of "detailed instructions to follow" in kits (see p. 4/5). In view of the teachings of Ahern, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the '941 claims so as to have packaged prepared kits including the components of '941 claims 5-7 as well as instructions for use of those components. An ordinary artisan would have been motivated to have made such a modification in order to have provided both the reagents of the '941 claims and the instructions for their use, for the advantage of allowing a

practitioner to properly employ the kit reagents more readily and efficiently, thereby saving the practitioner both time and money.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Diana B. Johannsen
Primary Examiner
June 24, 2004